

# KENDALL

HEALTHCARE PRODUCTS COMPANY

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Drive, Room 1-23  
Rockville, MD 20857

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Reference: Docket No. 97N-0477  
RIN 0910-ZA09

Kendall Healthcare Products Company would like to comment on the FDA proposal to revise or amend its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices. Because we are an original device manufacturer, we are quite concerned over the entire concept that another entity would try to place one of our devices into the same market with our trade name and approval marks, yet this action would be outside of our control. It would appear that the value basis for this action is the fact that the device carries a fully recognizable brand name and, therefore, well known performance expectations. If the FDA wishes to condone and support such business concepts, it should understand that there are considerable other issues in addition to the limited review that we are given the opportunity to comment upon as referenced above.

Question (1). Has FDA appropriately defined "refurbisher", "as-is remarketer", and "servicer" ?

- A. While we do identify and agree with the basic definition of refurbisher as offered, we are concerned with the ambiguity of the sentence dealing with preventive maintenance. If one assumes the devices are being prepared for resale or redistribution, then we would suggest any and all preventive maintenance procedures should be performed by the refurbisher at the time of handling the device. When we serve in a refurbishing role that is exactly what we do.
- B. The definition of as-is remarketer seems to stand apart from all other definitions concerning firms that provide devices to the medical marketplace, new or used. The appearance is the definition of a broker with no responsibility as to the quality of the device, its operational performance or its safety. To condone the existence of firms that can provide unqualified equipment to a customer seems to be out of step with the normal watchdog role of FDA. We do not believe it is correct practice to place the burden of initial performance testing upon the buyer prior to use on the patient. Unless the as-is remarketer can establish basic performance guarantees, then we do not believe such firms should be in the business of providing medical devices.
- C. The definition of servicer appears appropriate as worded. We do, however, see potential problems with alternate servicing firms not having complete access to manufacturer's documents due to proprietary issues. Full access to a device's design performance information seems to be implied in the proposed definition.

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Question (2) What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of the remarketing ?

We believe that in addition to being reactive, some degree of proactiveness is also necessary to at least consider the potential of certain types of problems.

In our experience of maintaining electronically based devices over a period of many years, we know first hand the challenge of performing repairs and maintenance once a device is several years old. Electronic parts often go obsolete even before the end of a product's short life span. We perform detailed analysis to confirm that, if we have to find an alternate component, it will be identical in performance to the original. We believe that most remarketers do not have the capability to do this kind of work.

Electronics packaging is getting smaller and allowing much more densely populated circuit boards. Operating voltages are going down. Many boards today are automatically built and tested. In a word, it is getting more difficult to repair individual components, thereby increasing risk. Components are more susceptible to electrostatic discharge, or ESD. Our documentation deals with how we build and test circuit boards and is not meant to be a repair guidance document. Such documentation falls into the category of proprietary information. Our service information which is available to the customer, guides the user through major subassembly replacement. We cannot and will not support board level refurbishing.

We make these points for consideration by FDA because we often see a rather pervasive attitude by many biomedical technicians that they can seek out and replace any faulty individual component. While this was more possible a few years ago, rapid advances in electronic design have increased the level of difficulty and risk many fold.

Question (3). What is the appropriate level of regulatory controls that should be applied to persons who remarket devices ?

We believe the answer to this question is the same level of assurance that the original device manufacturer has to meet. In addition, we believe that any device so handled by a remarketer should be thus labeled and that a new device record be started at the remanufacturer's site. It would also be our preference that the original manufacturer be notified of the type of service performed on the device and the date in order that we might close out our records properly.

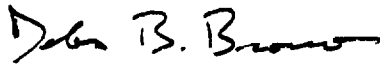
Question (4). Should refurbishers, as-is remarketers, and servicers be subject to the same or different regulatory requirements ?

We believe that refurbishers and alternate or third party servicers should be regulated to the extent that the full original device performance can be assured. The original device specification remains the same in the expectation of the customer. As-is remarketers should not exist in the device business, as by definition they do not offer any kind of performance assurance and expectations that the other categories are required to meet. For instance, many devices today carry a UL symbol, indicating not only initial adherence to a specific standard, but ongoing manufacturing adherence as well. If subsequent repairs cannot be maintained to UL standards by a remarketer, then the UL symbol should be removed from the device.

In summary, we believe if a specific defined device is marketed, having an identified brand name and product code, by a bona fide regulated manufacturer who meets and/or surpasses all applicable regulations, then that device is offered to the market and subsequent customers with stringent expectations. If, at a later time, other than the original customers are offered the same device, having the same recognizable brand name and code number, their expectations and assurances should be no less than the original conditions. If the above requirement cannot be met, then we see two clear choices; one, do not offer the device under the original brand and code number for resale, or two, rebrand and recode the device to a new specification and manufacturer.

We thank you for the opportunity to comment on this subject of great concern to us all. Please give our position as the original responsible manufacturer your careful consideration.

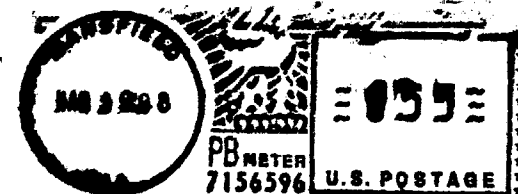
Sincerely,

A handwritten signature in black ink, appearing to read "Delos B. Brown". The signature is fluid and cursive, with the first name "Delos" and last name "Brown" clearly distinguishable.

Delos B. Brown  
Manager, Manufacturing Engineering

CC: Dr. David P. Miller,  
Director, Regulatory Affairs & Scientific Services

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